

REMARKS

Claims 1-5 and 10-17 are pending. Claims 6-9 have been canceled. Claims 10-16 have been withdrawn. Claim 17 is new.

The Examiner has rejected claims 3-5 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. In particular the Examiner indicates that it is unclear as to how cholesterol can be considered as a saturated lipid and cholesterol by itself does not form liposomes. Accordingly, claim 3 has been amended by deleting the term “cholesterol.” New claim 17, indicating that the composition further comprises cholesterol, is supported by examples 1-4.

The Examiner also indicates that the distinction between “phosphatidylcholine” and “natural phosphatidylcholine” is unclear, being also unclear the limitation in parenthesis. Finally, the Examiner indicates that natural phosphatidylcholines such as soy and egg are not saturated. Accordingly the parenthesis in reference to the expression “soy and egg” was deleted and the term “hydrogenated” in reference to natural phosphatidylcholines was included. This amendment is supported by examples 1-4.

In the present Office Action, claims 1-3 and 6-8 stand rejected under 35 USC 102 as being anticipated by Needham (US 2002/0102298) and WO 99/65466. Further, claim 9 stands rejected under 35 USC 103(a) as being obvious over Needham or WO 99/65466. Finally, claims 3-5 stand rejected under 35 USC 103(a) as being obvious over Needham or WO 99/65466 in combination with O'Brien (US 2002/064554). In view of the foregoing amendments and following remarks, the Applicant respectfully requests reconsideration of these rejections.

Independent claim 1 has been modified to incorporate all the features of dependent claim 9. In particular, independent claim 1 now recites that “encapsulated doxorubicin inside said liposomes in a ratio of about 8.5% by weight to about 11.5% by weight related to the total weight of lipids in the liposomes.” Such a limitation is supported by the following references in the application as originally filed: paragraph [0034] in US2006/0078605 publication, and examples 7-9.

The Needham (US 2002/0102298) and WO 99/65466 documents—both pertaining to the same patent family—address and disclose liposomes having a bilayer membrane comprising phospholipids and a surface active agent, wherein the liposomes release their contents at mild

hyperthermic temperatures. The Examiner asserts that although Needham and WO 99/65466 do not specifically teach how much of doxorubicin is encapsulated, the amount of the active agent incorporated within the liposomes depends upon various parameters such as the method of loading and the severity of the disease and therefore, deemed to be an obvious parameter manipulatable by an artisan. (Office Action, p. 4).

The Applicant draws the Examiner's attention to Examples 4 and 8 of Needham (US 2002/012298) wherein the doxorubicin entrapment procedure is described. In Example 4, the procedure of loading is carried out by incubation at 60°C. The amount of doxorubicin entrapped is not disclosed. In Example 8, the loading is carried out at 37°C, achieving 80% of the doxorubicin loaded into the liposome, which is considered "an improvement over the 30 or 40 percent loading that occurs using conventional loading techniques, namely a temperature of 60°C."

In the present application, by Examples 7-9, the inventor describes the obtaining of liposomes with 87.9 and 95.55 percent of doxorubicin loaded into the liposomes, which is higher than that of the prior art, as is required for cytotoxic agents.

For the foregoing reasons, amended claim 1 is not anticipated by or rendered obvious over the Needham US publication 2002/012298 or WO 99/65466. The inventor of the present application has achieved such higher load of doxorubicin into the small liposomes as claimed, on the basis of a method which is not described or suggested in any of the references cited by the Examiner. Thus, the amount of doxorubicin is not an obvious parameter manipulatable by an ordinary artisan. Reconsideration of the rejection of independent claim 1 is respectfully requested. Claims 2-6 depend either directly or indirectly from and add further limitations to independent claim 1 and are believed to be allowable for the reasons discussed hereinabove in connection with independent claim 1. Applicant reserves the right to further support the patentability of these dependent claims should that become necessary.

It is not believed that any fees are required with the submission of this response. However, if any fees are due, the Commissioner may charge appropriate fees to The H.T. Than Law Group, Deposit Account No. 50-1980, and if any extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a).

Respectfully submitted,

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